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McDERMOTT, WILL & EMERY			GORDON, BRIAN R	
600 13th Street, N.W.			ART UNIT	PAPER NUMBER
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DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/820,854	KAWAMURA, TATSUROU
	Examiner Brian R. Gordon	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on the interview summary of 6-14-05.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-9 and 11-25 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-9 and 11-25 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)  The translation of the foreign language provisional application has been received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_  
4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Specification***

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Response to Arguments***

3. Applicant's arguments filed May 19, 2005 have been fully considered but they are not persuasive as addressed in the Advisory Action (of June 7, 2005).

Applicant asserts each of the applied references do not disclose the step of "verifying that a predetermine amount of said sample solution is held in said sample cell based on a change over time in an output signal from said photosensor" and asserts both Pardikes and Laguana are directed to measuring the concentration of a component in a solution.

The examiner agrees both references do disclose measuring concentration. The examiner also submits that such a disclosure is equivalent to that as claimed by applicant. Applicant states that the polymer component is not a sample. The examiner, disagrees. As known in the art "a sample" may be considered to comprise numerous elements. A sample may be a portion of a whole element. One may also refer to an

entire whole as a sample. Merriam-Webster's Collegiate Dictionary, 10<sup>th</sup> ed., defines "sample" as a representative part of a single item from a larger whole or group esp. when presented for inspection or shown as evidence of quality (see attachment).

Applicant has not provided a special definition for the term "sample" within the specification. In light of such, the examiner asserts the polymer may be referred to as a sample and meets the broadest interpretation of the scope of the claims.

Furthermore, the term concentration is known as the measurement of "the amount of a component in a given area or volume." Applicant's claims do not recite a specific amount such as the total volume or any other limitations as directed to what the amount measured is limited to. The claim only requires that the amount be predetermined. As previously recited, Pardikes discloses continuously monitoring the concentration of a substance in order to maintain the concentration at a preselected value during the time of operation of the device. In order to maintain a level of concentration it is inherent that measurements are taken periodically during that time of operation to ensure that the concentration may be adjusted accordingly. Therefore, the assertion by applicant, the prior art is only directed to one end-result measurement, is incorrect.

Confirming/maintaining a concentration consists of verifying the presence of a predetermined amount of sample per area is held in the cell. The term "based on the change over time" does not mean that a change in the amount has to occur. Applicant step is a verification step that a predetermined amount is present over time. The claim does not recite that a change in the amount present in the cell has to occur over the

time period which verification is done. Broadly read the step, could be interpreted as simply a step in which one confirms/verifys that no change in the amount has occurred by taking periodic measurements. As such the examiner maintains the previous position for the reference of Pardikes discloses maintaining a particular concentration by continuously monitoring/measuring the concentratior over a time period.

Applicant further appears to assert that a measuring or confirming a concentration presence as taught by Pardikes and Laguana does not qualify as measuring/verifying "an amount". However, applicants claim 19 clearly "recites a method for measuring concentration of a solution". The method comprises the same verification step as recited in claim 1. Applicant's arguments clearly contradict what applicant claims for it is clearly implied that the verified amount is concentration.

Applicant also appears to imply that some calculation or computation is required in the claimed method. The claim states verifying. The step does not require taking the results of an output signal and inserting it into some type of equation to calculate a measurement. The step may simply be interpreted as monitoring the signal to see if it is maintained below, above, or at a certain reading.

For the reasons given above the examiner considers the prior art disclosures equivalent to that as claimed by applicant.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-6 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites: "said output signal over time is maintained at a first predetermined value or less for a first predetermined duration or longer." Or less than what? It is unclear what the "or less" refers to.

Claim 3 depends on claim 2 and recites: wherein the step (b) is a step of detecting an inflow of said sample solution into said sample cell based on the fact that said absolute value **has become a second predetermined value or greater**, followed by verifying that **said predetermined amount** of said sample solution is held in said sample cell based on the fact that said absolute value of an amount of change in said output signal over time **is maintained at the first predetermined value or less** for the first predetermined duration or longer, after detecting said inflow."

It is unclear what is meant by "or greater" and "or less". Or greater and or less than what? Applicant should specify what is meant by the phrases within the respective claims.

It is unclear how in claim 2 the absolute value is a first predetermined amount, then in claim 3 the first predetermined amount becomes a second predetermined amount, the said predetermined amount (what said predetermined amount? first or second?) goes to said first predetermined amount. What is the relationship of the first and second predetermined amounts. It is also unclear where exactly in the process the inflow is detected.

So based on claim 4 the value goes from small to larger back to small. It is unclear how such a change occurs within the method when applicant does not specify what is being measured and what factors allow for such changes to occur. There are intervening steps missing for one to determine how the method as claimed is performed.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims rejected 1-2, 6, 8-9, 11, 19, 21, 22, and 24-25 under 35 U.S.C. 102(b) as being anticipated by Pardikes, US 5,730,937.

Pardikes discloses, “a polymer processing system has a polymer input and an electrolyte input which may be varied independently of each other. The polymer and electrolyte are combined and mixed to provide an out flowing solution which flows through a sensor cell that gives an output signal indicating the concentration of polymer in the solution leaving the processing system. **The user repeatedly and incrementally sets the inflows of polymer and electrolyte to provide a preselected variety of concentrations of polymer in the out flowing solution.** On each incremental setting, a memory stores information relating the concentration to the output signal. Thereafter,

the processing system **automatically maintains any desired polymer concentration in joint response to the output signal and the stored information.**" (see abstract)

As recited above the process of maintaining a preselected concentration is equivalent to verifying a predetermined amount as claimed.

The device is an automatic controller in combination with a polymer processing and delivery system for continuously controlling production of a polymer solution during operation of said polymer processing and delivery system, said controller comprising optical analyzer means using coherent light (light for irradiating a sample solution) for continuously (over time) monitoring a concentration (verifying an amount) of polymer solids and controlling a polymer solids/hydrocarbon concentration of a polymer solution product at least while the system is in operation, said analyzer means including a sample chamber coupled to continuously receive and at all times contain an instantaneous aqueous sample of said polymer solution product, means for emitting said coherent light with a controlled amplitude and frequency into said sample, said light energy being scattered and absorbed by the polymer material dispersed throughout the instantaneous aqueous sample within the sample chamber, optical receiver means for measuring an amount of said coherent light energy received after said light passes through said instantaneous sample, means for converting an output from said receiver means into a usable process control signal for controlling said polymer system in order to maintain a desired concentration and viscosity in said liquid, wherein said automatic controller controls a concentration of any selected one of a plurality of different types of polymers in an out flowing solution of said polymer processing and delivery system, said

system including means for feeding an adjusted inflow of a selected polymer into said processing system, said selected polymer being one of said plurality of types of polymer, means for feeding an adjusted electrolyte inflow into said system, means for delivering an outflow from said system comprising a solution having a combination of said selected polymer and electrolyte with a concentration of said selected polymer fixed by a relative proportion of said inflow of said selected polymer to said inflow of electrolyte, said controller comprising said optical analyzer means using coherent light for continuously monitoring the concentration of said selected polymer in said out flowing solution, means for repeatedly adjusting a ratio of said inflows of said selected polymer and electrolyte, means responsive to said optical analyzer means for pre-storing a memory of an information curve for said selected polymer at each of said repeated adjustments, means for repeating said selection of polymers with a different polymer being selected on each repeated selection, said repeated adjustments being made for each of said different polymers until information curves have been stored in memory for all of said plurality of types of polymer, said information curve memories representing at least an output of said optical analyzer means said concentration for each of said plurality of types of polymer in said out flowing solution, means jointly responsive to said stored information curve memories derived from said repeated adjustments and to an output of said optical analyzer means for providing a usable process control signal for controlling said system, and means responsive to said process control signal for adjusting said inflows of polymer and electrolyte to maintain a selected concentration of any selected one type of polymer in said solution in order to

Art Unit: 1743

process said selected one type of polymer. (see column 11, line 61 – column 12, line 51; claim 1)

9. Claims rejected 1-2, 8-9, 11, 14-15, 19, 21, and 22 under 35 U.S.C. 102(b) as being anticipated by Laguna et al., US 5,871,698.

Laguna et al. discloses a chemical probe that can determine the concentration (verifying amount) of given chemicals in a fluid. The chemical probe has a reaction volume wherein the fluid to be analyzed (the analyte) can react with a known reagent. The chemical probe has means for launching light into the reaction volume, through the analyte/reagent reaction, to a collection point. The collected light can be analyzed to determine absorption properties of the analyte/reagent reaction, allowing determination of the concentration of the chemicals of interest in the analyte. The chemical probe allows the reaction volume to be flushed of the previous reaction, allowing multiple unattended measurements. The probe also provides for relatively slow analyte transport into the reaction volume and reagent transport out of the reaction volume, allowing measurements to be made directly in a large source of analyte without significantly contaminating the analyte. The chemical probe is well suited for in situ measurements because it can be made more compactly than previous chemical probes (column 1, lines 49-68).

FIG. 1 is a simplified diagram of a probe according to the present invention.

Reaction volume 101 connects with reagent input means 110 for introducing a reagent into the reaction volume, analyte means 120 for introducing a chemical to be analyzed (the analyte) into the volume, flush means 150 for flushing the residue of the reaction,

light launch means 130 for launching light into the reaction volume, and light collection means 140 for collecting light from the reaction volume. In operation, a reagent is introduced into the reaction volume 101 via the reagent means 110. Analyte is introduced into the reaction volume 101 via the analyte means 120. As the reagent and analyte react, the light absorption properties of the fluid in the reaction volume 101 will change. The change in absorption properties can be determined by launching light into the reaction volume 101 via the light launch means 130 and collecting the light via the light collection means 140 after the light passes through the reaction volume 101 (measuring change over time). The determination can be done when the reaction is complete or in time as the analyte flows in to the reaction volume. The reagent can be chosen so that the reaction product's absorption properties vary based on the concentrations of predetermined chemicals in the analyte. The absorption of the launched light, as measured by the collected light, can thus be used to determine the relative concentrations of predetermined chemicals in the analyte. The reaction products can then be flushed from the reaction volume via flush means 150, and a new determination made by introducing new reagent and analyte into the reaction volume 101 (column 2, lines 32-60).

As recited above the determination of the concentration may be done in time or operation of the device. This is considered equivalent to applicants verifying step.

FIG. 7 is a schematic view of the reagent/waste portion of a chemical probe according to the present invention. A spring-loaded bellows reservoir 715 stores a quantity of reagent. The reservoir 715 can be filled via a fill port 714, such as a septum.

Reagent flow through reagent fill tube 711 to the reaction volume 701 is controlled by a valve 713. The flow passes through a filter/frit 712, which controls the reagent flow rate and prevents particle contaminants from reaching the reaction volume 701.

Reagent/analyte reaction products are carried from the reaction volume 701 to a spring-loaded bellows reservoir 755 through flush tube 751. Flow through flush tube 751 is controlled by a valve 753. Waste fluid can be removed from the reservoir 755 via a waste removal port 754 such as a septum. The use of spring-loaded bellows reservoirs places the fluid in the system under positive pressure. Positive pressure prevents the formation of bubbles, important because bubbles can dramatically change the light absorption characteristics of the fluid in the reaction volume and thus impair the accuracy of the probe. In operation, valve 753 opens first. After about one second, valve 713 opens, allowing fresh reagent into the reaction volume 701. After about 2 seconds, valves 713, 753 both close and the light absorption measurements are performed (column 4, line 60 – column 5, line 16).

3. Claims 1-2, 5-6, 8-9, 11-12, 19, 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hewett, US 5,110,724.

Hewett discloses an assay device for assaying multiple analytes in a drop-size blood sample (abstract).

Apparatus 66 further includes a light source 74 which produces directed light beams, such as beam 76, which are directed at an angle against each reaction pad, with the sample-transfer device in housing (sample cell). For each pad, a light detector, such as detectors 78, 80 associated with pads 48, 50, respectively, is provided for

monitoring the extent to which the expanse of the pad is wetted during delivery of the sample to the surface region of the pad. More specifically, during sample transfer, as liquid sample migrates into and through a pad, the reflectivity of the surface of the pad will decrease, due to the greater translucency of the pad, which is typically white and relatively reflective in its dry condition. Thus, as the pad is wetted by the migration of liquid sample through the pad, the intensity of the reflectance beam measured by the associated detector until the pad becomes completely wetted (predetermined amount). Typically, when **reflectance was measured as a function of time** after first contact between the pads and dispenser, all of the pads in the test plate showed a sharp decrease in reflectance, over an approximately 2 second time period, after which reflectance plateaus, indicating complete wetting of the pad. Each pad wetted completely at about the same rate. The detector may be coupled to a microprocessor designed to calculate total sample volume (predetermined amount) transfer to each pad, as described in the above-mentioned co-pending patent application, Ser. No. 320,474. Once the time required for optimal pad wetting has been measured, or calibrated, the apparatus may be operated for optimal sample-transfer by placing the device in a sample-transfer condition for the calibrated time period (beginning at column 6, line 35).

The detector is also used to measure the change in reflectance in the associated pad due to the production of a colored reaction product in the pad, as analyte is utilized in forming the reaction product, after pad wetting occurs. As can be appreciated, when the light beam of the light source has a wavelength at or near the absorption maximum

of the colored reaction product, the reflectance from the pad will decrease gradually with continued production of reaction product, until a new (second) reflectance-curve plateau is reached at the end point of the reaction. The total amount of analyte can then be calculated from the difference in reflectance at the first plateau (just after pad wetting) and at the second plateau (at the product end point).

Based on the calculated volume of sample applied to a pad, and the amount of analyte contained in the volume, as determined by an analyte-dependent chemical reaction in the pad, the concentration of analyte in the sample can then be determined by the calculator.

One exemplary three-pad device, designed for determination of total serum cholesterol and triglyceride, contains in each pad (claim 12).

4. Claims 1-6, 8-9, 11-13, 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeige et al. US 5,100,805.

Zeige et al. disclose an improved, copolymer-based immunoassay system, method, and apparatus is highly sensitive and effective in accurately measuring extremely low concentrations, such as  $10^{-6}$  to  $10^{-12}$  grams per milliliter, of biologically active substances, such as monoclonal or polyclonal antibodies and antigens, cancer markers, proteins, bacteria, viruses, therapeutic drugs, drugs of abuse, and food and water contaminants in fluid samples (abstract).

Disclosed is a method, and apparatus for quantitatively measuring the concentration of a biologically active substance, such as an antigen or an antibody, in a body fluid such as blood, serum, urine, or plasma by initiating an agglutination reaction

in a mixture comprising a fluid sample and a reagent, and by measuring the extent of the agglutination reaction over time.

The system further includes a new means for illuminating such an agglutination reaction through a transparent container with high-intensity light and for detecting light scattered by such polymeric particles during the agglutination reaction. A detector detects light scattered by the mixture in a forward direction at an acute angle within a range from about 10.degree. to about 20.degree. relative to the path of the illuminating light and generates output signals proportional to the intensity of the detected scattered light. The system further includes means to digitize the output signal of the detector; memory means for receiving and storing digital data representing the intensity of the detected scattered light at a specified time, or times, during a test, for storing standard curve data representing the concentration of a substance of interest as a function of detected light intensity at a specified time, or times, during a test and for storing a system-operating program; means for comparing the stored test data in the memory means with the standard curve data in the memory means; and output means coupled to said comparing means for providing a quantitative measure of the concentration of the substance of interest in the fluid sample. The system of the invention can also store and compare the rate of change of such test data and standard curve data at various times during a test (beginning at column 4, line 40).

For example, where the method of the invention tests for Theophylline, a widely prescribed bronchial dialator (anti-asthma drug), the preferred format is indirect and the method preferably includes the steps of providing a reagent solution comprising at least

a buffer and an anti-Theophylline antibody; providing a reagent suspension comprising a buffered suspension of the sensitized uniformly sized copolymer particles with attached Theophylline antigen, preferably Theophylline-8-hydroxypropylamine; mixing the reagent solution with a serum test sample; mixing the reagent suspension with the mixture of the first reagent solution and the test sample; passing the high-intensity column of light through the mixture of test sample, reagent solution, and reagent suspension; measuring the intensity of the light scattered by the mixture at an acute angle (claims 13 and 20) to the light column as a function of time; storing data on the scattered light intensity **as a function of time**; and comparing the stored data with test data to determine the concentration of the substance of interest in the fluid sample (beginning at column 5, line 47).

The intensity of the light scattered by the mixture in a forward direction at a given angle  $\theta$  is proportional to the number of particles of given size in mixture 97, and hence, is proportional to the extent of an agglutination reaction that has taken place in the mixture. The intensity of scattered light in the forward direction is initially small since at the beginning of the reaction, the mixture will contain mostly monodisbursed particles of small size. As the agglutination reaction progresses, however, the monomers come together to form agglomerations which are larger in size. These agglomerations scatter the light that can be measured as an increase in the intensity of scattered light at the angle  $\theta$  in the forward direction. The change of intensity is proportional to the change in the number of agglomerations in the mixture; and the rate of change of intensity of scattered light in the forward direction is proportional to the rate of

agglutination, which, in turn, is indicative of the concentration of the biologically active substance of interest in the test sample.

During a test, analog intensity signals from photodetector 48 are converted to digital signals by analog-to-digital converter 56 and transmitted to microcontroller 62 which stores data indicative of the detected, scattered light intensity at angle  $\theta$ , preferably as a function of time, in RAM memory 64. This test data is then processed for comparison with standard curve data, which represents the concentration of a substance of interest. The data may be processed to determine concentration from reaction "end-point" data (i.e., data at a specified time) and/or the rate of change of the reaction and/or the maximum rate of change of the reaction, as determined from the measurements of the scattered light intensity over time.

5. Claims 1-2, 5-6, 8-9, 11, 19, 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Eseifan US 4,436,822.

Eseifan discloses A mixing system and method for analyzing a specimen.

FIG. 1, a specimen analyzing system 10 is shown including a reagent mixing system 12 in accordance with the present invention. While the mixing system 12 may be used in various types of specimen analyzing systems, for example, of the type that detect electrical or chemical characteristics of a sample and reagent, a mixing system of the present invention is particularly useful in specimen analyzing systems which detect optical characteristics such as transmittance, concentration, light absorbance, rate of change of light absorbance, and others. The detecting of such optical characteristics are useful in medical testing, for example, in the determination of clotting time of blood

plasma, concentration (an amount) of creatinine, and in many other medical determinations (beginning at column 1, last line).

The analyzing system 10 is shown including an optical detecting system or spectrophotometer diagrammatically shown at 14. The optical detection system 14 is shown including a specimen container or cuvette 16 positioned in a well 18 of a plate 20 of a housing for the apparatus. A light source 22, preferably a high intensity lamp, for example, a halogen lamp, is mounted to the housing plate 20 to pass a light beam through a focusing lense 24 and a filter 26 mounted in the housing on one side of cuvette 16. The filter is chosen to allow the passage of light at wavelengths which are in accordance with the characteristic of the specimen to be analyzed. Light passing through the cuvette 16 from lamp 22 is received by a light detector or light transducer 28 mounted in the housing on the opposite side of the cuvette. The detector 28 produces an electrical signal output proportional to the transmittance of the specimen in the cuvette 16. The lamp 22 is enegized by a voltage supply source 30. The detector 28 has its output connected to a conventional signal amplifier 32 having its output connected, for example, to a suitable or conventional programmed computer system 34. The computer system 34 is shown connected to a read-out display device 40. The computer system 34 is shown energized by a power supply indicated at 42 through an on-off switch 44. A "test" switch for manually starting the programmed operations of the computer system to effect a test on the sample in the cuvette is indicated at 45.

Depending upon the particular test desired, the computer 34 may be programmed to provide a read-out at device 40 that is related to optical density or a

change in light absorbance or other optical characteristic of the desired or particular solution of reagent and specimen under consideration. For example, the detection of a rate (over time) of change in transmittance by detector 28 can be used to calculate a change in absorbance and be used by the computer to determine, for example, the concentration of creatinine in a sample of urine. The reagent used in such case may be picrate (picric acid and an alkaline solution).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-9 and 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. US 4,943,416 further in view of Zeige et al. or Eseifan (or vice versa).

Kikuchi discloses an automatic urinalysis system which can be readily installed at an excretion site such as a toilet and by which means a subject itself can test its urine easily at any time and can obtain results of such test. The system comprises a sample

collecting means for collecting a sample of urine within a stool or the like at an excretion site, a guiding means for introducing the collected urine sample into a testing area within a body of the system, a urine testing element located within the system body, a contacting means for automatically contacting the urine testing element with the urine sample in the testing area, a urine testing means for automatically testing the urine testing element contacted with the urine sample by the contacting means, a display means for displaying test data from the urine testing means, and a discharging means for discharging the urine sample into the stool after the urine sample has been contacted by the urine testing element (abstract).

After testing, the storage chamber and some other components of the automatic urinalysis system 1 which have contacted with the urine are washed and/or sterilized by a washing and/or sterilizing means 11 (claims 14-15).

While Kikuchi et al. disclose a urine level sensor, Kikuchi does not disclose measuring or verifying an amount over time.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system and method of Kickuchi et al. of Zeige et al. or Eseifan et al. (as described above) for the medical community has a continuing need for improved procedures for measuring the concentration of biologically active substances, e.g., antigens and antibodies, in body fluids. Such procedures are needed, for example, to measure the concentration of drugs, hormones, and other substances in blood, serum, plasma, urine, and other body fluids as an aid in medical diagnosis and in the administration of drugs (Zeige et al. column 1 line 14) and to provide an automatic

urinalysis system which can easily and frequently test and analyze urine and can provide information of results of such analysis to a subject at an excretion site such as a toilet of a hotel, a department store, a firm or a house of the subject itself at which the automatic urinalysis system is installed without the necessity for the subject to take the trouble to go to a hospital or a medical testing center in order to undergo a medical testing of urine performed thereat by a doctor and/or a nurse (Kikuchi et al. column 2, line 1).

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lemke, John et al.; Wardlaw, Stephen C.; Matsubara, Shigeki et al.; Shinn; Alan et al.; Harrison; Daniel Jed et al.; Elrod; Scott A. et al.; Wardlaw; Stephen C.; Gui; John Yupeng et al.; Safir; Adam et al.; Petro; Miroslav et al.; Tajima; Hideji; Janik; Gary R. et al.; Ridgeway; Helen J. et al.; Stimpson; Donald Irvine et al.; Pugh; Jerry Thomas; Samuels; Brian C. et al.; Hulette; William C. et al.; and Kawai; Shoji et al. disclose various analytical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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